



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/524,211

02/10/2005

Kaoru Usui

050053

6407

23850 7590 10/22/2009
KRATZ, QUINTOS & HANSON, LLP
1420 K Street, N.W.
Suite 400
WASHINGTON, DC 20005

EXAMINER

YAGER, JAMES C

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

10/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,211	Applicant(s) USUI ET AL.	
	Examiner JAMES YAGER	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20090803</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 10 June 2009 has been entered. Claims 1-5 are currently pending in the application. The rejections of record from the office action dated 10 March 2009 not repeated herein have been withdrawn.

Information Disclosure Statement

2. Regarding the Information Disclosure Statement dated 03 August 2009, the reference "Japanese Office Action dated 07/07/09" was not considered because no English translation was provided.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1794

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (US 5,046,479) in view of Donati et al. (US 6,379,695), and Kaplow et al. (US 3,769,042).

Regarding claims 1 and 5, Usui discloses a heat-generating body, comprising a heat-generating portion formed by sealing a heat-generating composition causing an exothermic reaction in the presence of air (col 2, ln 23-35) in an air-permeable container in desired form such as bag form or sheet form (col 2, ln 35-36) and an adhesive portion (col 2, ln 35-40) to enable the heat-generating body to be attached to skin (col 1, ln 10-11).

Usui does not disclose the adhesive portion comprising, as a main component, a water-containing hydrophilic gel agent obtained from a hydrophilic polymeric thickening agent, wherein an organic filling agent is added in the water-containing hydrophilic gel agent in the adhesive portion.

Donati discloses an adhesive plaster for use on skin (C1/L54-58) comprising an adhesive hydrogel matrix and a thickener such as carboxymethylcellulose (i.e. a water-

Art Unit: 1794

containing hydrophilic gel agent obtained from a hydrophilic polymeric thickening agent) (C2/L25-27; C2/L48-56). Donati discloses that the adhesive can contain active ingredients for treating the skin (C2/L8-15)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the hydrogel adhesive disclosed by Donati as the adhesive in the heat-generating body of Usui, since Usui and Donati are in the same field of endeavor (adhering an apparatus to the skin of a person), and to provide a heat-generating body having the advantage of a skin treating agent in the adhesive to treat the skin of a patient.

Neither Usui nor Donati disclose that the difference between critical moisture values of the heat-generating portion and the adhesive portion is 2% or less.

Kaplow discloses a beef stew formulation wherein the beef chunks, carrots, peas and potatoes are dehydrated to a moisture content of less than 45 percent and a gravy with a moisture content of 45 percent or less (i.e. difference of 2% or less) and that the respective moisture contents of the solids phase and liquid phase will approximate one another such that moisture migration between the phases will be minimal and therefore not adversely imbalance the concentration of stabilizing solutes in the phases (C2/L18-48).

The examiner recognizes that Kaplow is used for food, however, the reference is being used to teach the concept of maintaining equilibrium of moisture content of

Art Unit: 1794

adjacent entities to prevent the migration of water, which clearly applies to the context of the heat-generating composition and adhesive set forth in Usui and Donati.

Although Kaplow discloses moisture content not critical moisture value, it is the examiner's position that these values will be directly related to one another and therefore, a percentage difference between two moisture content values and two critical moisture values will be directly related.

Given that Usui discloses that an appropriate degree of moisture is important to provide good heat generating ability of the heat generating composition and too much or too little moisture negatively affect heat generating ability (C2/L64-C3/L10), it would have been obvious to one of ordinary skill at the time the invention was made to minimize the difference between the moisture content of the adhesive composition and the heat generating composition to minimize water migration between the adhesive composition and the heat generating composition as suggested by Kaplow to provide a heat generating body that has a heat generating composition that maintains effective heat generating properties.

Alternatively, it is the examiner's position that is well known to one of ordinary skill in the art that water migrates from an area or article having high moisture content to an adjacent area or article having low moisture content. Given that Usui discloses that an appropriate degree of moisture is important to provide good heat generating ability of the heat generating composition and too much or too little moisture negatively affect heat generating ability (C2/L64-C3/L10), it would have been obvious to one of ordinary

Art Unit: 1794

skill at the time the invention was made to minimize the difference between the moisture content of the adhesive composition and the heat generating composition to minimize water migration between the adhesive composition and the heat generating composition, as readily apparent to one of ordinary skill in the art, to provide a heat generating body that has a heat generating composition that maintains effective heat generating properties.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (US 5,046,479) in view of Donati et al. (US 6,379,695) and Kaplow et al. (US 3,769,042), as applied to claim 1 above, in further view of Ayers (US 2,507,465).

Regarding claim 2, modified Usui discloses all of the claim limitations as set forth above. Modified Usui does not disclose that an organic filling agent is added in the water-containing hydrophilic gel agent in the adhesive portion.

Ayers discloses organic filler for use in an adhesive that promotes the adhesive quality (C1/L40-46).

Usui, Donati and Ayers are analogous art because they all teach about adhesives. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the organic filler of Ayers into the adhesive of modified Usui to provide a heat generating body having an adhesive with better adhesive quality.

7. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (US 5,046,479) in view of Donati et al. (US 6,379,695) and Kaplow et al. (US 3,769,042), as applied to claim 1 above and over Usui (US 5,046,479) in view of Donati

et al. (US 6,379,695), Kaplow et al. (US 3,769,042) and Ayers (US 2,507,465) as applied to claim 2 above, further in view of Otsuka et al. (US 2001/0010847).

Regarding claims 3 and 4, modified Usui discloses all the claim limitations as set forth above. Usui further discloses that the heat-generating body is contained in an air-tight container bag (col 1, ln 16-20, wrapped, hermetically sealed bag). Additionally, Usui discloses that the adhesive portion is attached to the heat-generating portion (col 2, ln 32-37), but does not explicitly disclose how they are attached. Otsuka discloses a heat-generating body comprising a heat-generating portion and an adhesive portion ([0050]) wherein the adhesive portion is laminated on the heat generating portion ([0061]-[0062], stacked laminate).

As Usui is not limited to any specific examples of attachment and as laminating adhesives to heat-generating bodies is well known in the art at the time the invention was made, as evidenced by Otsuka, and further, as the instant specification is silent to unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to laminate the adhesive onto the heat-generating portion as in the heat-generating body of Otsuka. Said combination would amount to use of a known attachment method for its intended use in a known environment to accomplish entirely expected result.

Response to Arguments

8. Applicant's arguments filed 10 June 2009 have been fully considered but they are not persuasive.

Applicant argues that it is improper to assert that one of ordinary skill in the art would achieve the recited difference between the critical moisture values of 5% or less without such a teaching since this would be an improper hindsight reconstruction.

As set forth above, it is the examiner's position that is well known to one of ordinary skill in the art that water migrates from an area or article having high moisture content to an adjacent area or article having low moisture content. This is readily known to anyone having a modicum of understanding of the concepts of tonicity and osmotic pressure.

Additionally, Usui provides motivation to consider adjusting moisture content given that Usui discloses that an appropriate degree of moisture is important to provide good heat generating ability of the heat generating composition and too much or too little moisture negatively affect heat generating ability (C2/L64-C3/L10). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to minimize the difference between the moisture content of the adhesive composition and the heat generating composition to minimize water migration between the adhesive composition and the heat generating composition, as readily apparent to one of ordinary skill in the art, to provide a heat generating body that has a heat generating composition that maintains effective heat generating properties.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that Kaplow teaches that the migration of stabilizing solutes between the phases will be minimal to adversely imbalance the concentration of stabilizing solutes and that it differs from the instant invention because the instant invention teaches that the difference in moisture values of the heat-generating portion and the adhesive portion is 2% or less and that transfer of moisture between the portions does not occur and the performance of the heat-generating body and the adhesive are not deteriorated.

Contrary to applicant's assertion, Kaplow clearly discloses that the respective moisture contents of the solids phase and liquid phase will approximate one another such that moisture migration between the phases will be minimal (C2/L40-45). In other words, Kaplow discloses maintaining equilibrium of moisture content of adjacent entities to prevent the migration of water.

Applicant argues that the critical moisture value of the present invention is a value indicating relative moisture in a state in which, at a certain relative humidity, moisture in the heat generating portion or the adhesive portion is in an equilibrium state.

As set forth above, although Kaplow discloses moisture content not critical moisture value, it is the examiner's position that these values will be directly related to one another and therefore, a percentage difference between two moisture content values and two critical moisture values will be directly related. Applicant provides no evidence to the contrary.

Applicant argues that it is improper to allege that one of ordinary skill in the art would turn to the teaching of Kaplow in the food art and use such teaching in a heat generating body.

The examiner recognizes that Kaplow is used for food, however, the reference is being used to teach the concept of maintaining equilibrium of moisture content of adjacent entities to prevent the migration of water, which clearly applies to the context of the heat-generating composition and adhesive set forth in Usui and Donati.

Applicant argues that there is no suggestion to motivate one of ordinary skill in the art to combine the teachings of Usui and Kaplow.

As set forth above, the motivation to combine Kaplow with Usui is provided in the Usui reference itself, which discloses that an appropriate degree of moisture is important to provide good heat generating ability of the heat generating composition and too much or too little moisture negatively affect heat generating ability (C2/L64-C3/L10). Therefore it would have been obvious to one of ordinary skill at the time the invention

Art Unit: 1794

was made to minimize the difference between the moisture content of the adhesive composition and the heat generating composition to minimize water migration between the adhesive composition and the heat generating composition as suggested by Kaplow to provide a heat generating body that has a heat generating composition that maintains effective heat generating properties.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES YAGER whose telephone number is (571)270-3880. The examiner can normally be reached on Mon - Fri, 7:30am-5pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JY 1012/09

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1794